NHS
North East London

December 2025

Guidance Note on Rybelsus® (oral semaglutide): managing the risk of medication errors due to the introduction of a new formulation with increased bioavailability

This guidance note applies to all primary care clinicians in North East London. It has been developed to support clinicians in managing the risk of medication errors due to the introduction of a new formulation of oral semaglutide with increased bioavailability.

Novo Nordisk® UK recently published a **direct healthcare professional communication** to inform that Rybelsus® tablets will be replaced with a new formulation with increased bioavailability. The tablet strengths are different and new excipients have been included to modify absorption. The new formulation is bioequivalent to the initial formulation as described in the table below:

Initial formulation (one oval tablet)	Bioequivalence	New formulation (one round tablet)
3mg (starting dose)	=	**1.5mg (starting dose)**
7mg (maintenance dose)	=	**4mg (maintenance dose)**
14mg (maintenance dose)	=	**9mg (maintenance dose)**

Rybelsus® is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise. The new formulations are now available in the British National Formulary (BNF), to prescribe on GP prescribing systems and to order from pharmacy procurement systems. It is anticipated that the old formulation will be available to order until at least **31st January 2026**. Therefore, patients will need to have their prescriptions reviewed and changed over to the equivalent strength of the new formulation before this date.

Key Safety information:

- The new formulation has the same efficacy, safety and method of administration as the initial formulation.
- Rybelsus® tablets should always be taken as one tablet per day.
- The two formulations will temporarily co-exist on the market, which may cause mix-ups. This could result in overdosing, which increases the risk of adverse events e.g. nausea, vomiting, diarrhoea and abdominal pain.
- Patients currently taking Rybelsus® should be informed and advised about the change in formulation and dose when the new formulation is prescribed and dispensed.
- Patients initiating Rybelsus® treatment should be prescribed the new formulation and informed by both the prescriber and pharmacist that two formulations are currently available. Patients already taking Rybelsus® should also be advised on when to transition to the new formulation, when to discontinue the old formulation, and how to safely dispose of any remaining supplies of the old stock.
- **A patient information leaflet** has also been published to support primary care clinicians with transferring patients from the old formulation to the new formulation.

- The NEL ICB pharmacy and medicines optimisation team included information regarding the formulation change in the September [1] [2] and November 2025 [3] [4] newsletters. The NEL Formulary has been updated to reflect the introduction of the new formulation and new safety alerts will also be available on OptimiseRx.

Actions for Healthcare Professionals

General practice and primary care networks

Primary care prescribing clinicians (e.g. general practitioners and non-medical prescribers) and pharmacists in general practice and primary care networks should:

1. Familiarise themselves with the new dose formulation and information and share with relevant colleagues to ensure patient safety and avoid prescribing & dispensing errors.
2. Patients starting Rybelsus® treatment should be prescribed the new formulation and be suitably informed by the prescriber that two formulations temporarily co-exist on the market.
3. Patients currently taking Rybelsus® should be switched to the bioequivalent new formulation and be informed of the change, and a prescription note added to the prescription for the commuity pharmacy.
4. Patients currently taking Rybelsus® should also receive clear instructions on when to begin the new tablet formulation, when to discontinue the old formulation, and how to safely dispose of any unused tablets, in accordance with their individual medicines administration requirements.
5. Add a prescribing note on the clinical system to flag the change for all patients on Rybelsus®.
6. Please double check that the old formulation strength is removed from the current medicines list at the time of transferring patients from the old formulation to the new formulation.
7. Share the **patient information leaflet** with patients/carers which explains the changes to the Rybelsus® formulation.
8. Report any suspected adverse drug reactions (ADRs) including medication errors to the Yellow Card scheme.
   You can report via:
   - The Yellow Card website - **https://yellowcard.mhra.gov.uk**
   - The free Yellow Card app available from the Apple App Store or Google Play Store.
   - Some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals.
   - Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

Community Pharmacy

Community pharmacists and community pharmacy teams should:

1. Familiarise themselves with the new dose formulation and information and share with relevant colleagues to ensure patient safety and avoid prescribing & dispensing errors.
2. Check prescriptions carefully for clarification where patients are switched; please contact the prescriber if this is not clear.
3. Counsel patients on formulation change and ensure they are aware not to double up their dose where a lower strength formulation is dispensed (e.g. not to take 2 x 1.5mg for a previous 3mg dose).
4. Confirm with patients or carers whether they have been advised on when to start the new formulation and stop the old one. If not, or if there are specific administration needs, provide guidance, contacting the prescriber where needed. Accept any unwanted medicines for safe disposal.
5. Consider use of shelf separation or labelling in dispensaries while both formulations are in circulation.
6. Report any suspected adverse drug reactions (ADRs) including medication errors to the Yellow Card scheme.
   You can report via:
   - The Yellow Card website - https://yellowcard.mhra.gov.uk
   - The free Yellow Card app available from the Apple App Store or Google Play Store.
   - Some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals.
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Counselling Points

Actions for Patients Taking Rybelsus® (oral semaglutide)

1. **Know what's changing**
   - Rybelsus® tablets are changing shape from *oval* to *round.*
   - The new tablets help your body absorb the medicines better.
   - The strength printed on the pack (e.g. the number of milligrams) may look different to the old version but your treatment will work the same.
   - The new box is smaller but the logos on the boxes are the same as the old version.
2. **Understand the new tablet strength**
   - Old 3mg tablet → New 1.5mg tablet
   - Old 7mg tablet → New 4mg tablet
   - Old 14mg tablet → New 9mg tablet
     These changes do not mean you are getting less medicine. It is just a different way of making the tablets.
3. **Take only one tablet once a day**
   - Do **NOT** take two of the new lower-strength tablets to make up the old dose.
   - Always take **just ONE tablet daily**, as advised by your doctor and pharmacist.
   - Take your new Rybelsus® tablets the same way you did before.
4. **Check your prescription and your tablets**

- Your prescription may show a different strength of tablet than before.
- This does not mean your dose (number of mg) has been reduced; it is simply a new version of the medicine.
- If you're unsure, ask your pharmacist or GP to confirm.

5. **Watch for side effects**
   - Some people may feel sick or have an upset stomach, especially if the dose is wrong.
   - If you feel unwell or think you may have taken the wrong dose, contact your healthcare professional straight away.
6. **Report any side effects**
   - The UK has a national system called the Yellow Card Scheme, which helps monitor the safety of medicines and vaccines.
   - You can report side effects online at **https://yellowcard.mhra.gov.uk** or via the free Yellow Card app.
7. **Safely dispose of unwanted medicines**
   - Always return any unused or unwanted tablets to your pharmacy.
   - Do not throw medicines in household or public bins, as this can harm others and the environment.
   - Your pharmacist will dispose of them safely for you.
8. **Ask questions if you are unsure**
   - If you are starting Rybelsus® for the first time, you should receive the new tablets. If you are already taking Rybelsus®, you will be switched to the new version.
   - Read the **patient information leaflet** and check **Diabetes UK** for more details.
   - Always check with your pharmacist or GP if anything looks different or confusing.

Please continue to record suspected adverse drug reactions to the Yellow Card scheme.

Please continue to record medicine patient safety incidents to Learning From Patient Safety Events.

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